

WHAT IS CLAIMED IS:

1 1. A handheld ultrasound device weighing less than fifteen pounds,
2 including a transducer, beamformer and image processor and a first digital signal processor
3 capable of processing B mode and flow (2D Doppler) scans, having an second digital
4 processor block comprising:

5 a digital Doppler QBP filter (FPGA) for filtering PW Doppler signals; and
6 a second digital signal processor core for PW Doppler signal processing.

1 2. The handheld ultrasound device of claim 1, more preferably weighing
2 less than ten pounds.

1 3. The handheld ultrasound device of claim 1, even more preferably
2 weighing less than seven pounds.

1 4. The handheld ultrasound instrument of claim 1, wherein the first
2 digital signal processor, the second digital signal processor and the FPGA are unified onto a
3 single application specific integrated circuit (ASIC) chip.

1 5. The handheld ultrasound device as described in claim 1, wherein the
2 beamformer, image processor, first and second digital signal processors and FPGA are
3 integrated into a single ASIC chip.

1 6. The handheld ultrasound device of claim 1, wherein the second digital
2 signal processor for performing M mode interpolation, digital Doppler QBP filtering and PW
3 Doppler signal processing are located on a digital signal processing application specific
4 integrated circuit (ASIC) chip.

1 7. The handheld ultrasound device of claim 1, further comprising a time-
2 motion display capability (M mode) wherein the M mode signal processing occurs on the first
3 digital signal processor using a micro-code block, and interpolation of M-mode signal for
4 video display is done on the second digital signal processor.

1 8. The handheld ultrasound device of claim 1, further comprising a means
2 for performing tissue harmonic imaging.

1 9. The handheld ultrasound device of claim 1, further comprising a serial
2 I/O port for sending and receiving data to peripheral devices.

1 10. The handheld ultrasound device of claim 1, further comprising a CW
2 Doppler circuit having a CW beamformer ASIC and a supplemental circuit for A/D filtering
3 and performing analog to digital conversion on I and Q signal pairs, wherein the FPGA of the
4 second digital processor block processes complex data at a constant sample rate prior to
5 processing through the second digital signal processor core.

1 11. The handheld ultrasound device of claim 10, having circuitry for
2 performing transmit and receive signal control combined with a CW beamformer on a single
3 ASIC chip, and having I/O ports for access to other process circuitry (2D, M mode, B mode).

1 12. An ultrasound diagnostic instrument comprising:
2 a) a handheld module including a display, manual controls, and system
3 circuitry for processing signals for display;
4 b) a transducer assembly coupled to the system circuitry for providing
5 electrical signals from ultrasound waves for processing; and
6 c) an electrocardiograph (ECG) module coupled to the handheld module
7 by a cable and including leads for receiving ECG signals from a patient and ECG signal
8 processing circuitry for applying ECG signals to the handheld module through the cable.

1 13. The ultrasound diagnostic instrument as defined by claim 12, wherein
2 the ECG module receives control and power signals from the handheld module.

1 14. The ultrasound diagnostic instrument as defined by claim 12, wherein
2 the signal processing circuitry of the ECG module includes first amplification and filtering
3 circuitry for signals from the leads and second amplification and filtering circuitry for
4 processing signals from the first amplification and filtering circuitry for application to the
5 handheld module, the first and second amplification and filtering circuitry being electrically
6 isolated whereby a patient is electrically isolated from the handheld unit.

1 15. The ultrasound diagnostic instrument as defined by claim 14, wherein
2 the first amplification and filtering circuit receives electrical power from the handheld

3 module, the electrical power being capacitively coupled to the first amplification and filtering
4 circuitry.

1 16. The ultrasound diagnostic instrument of claim 15, wherein the
2 transducer assembly is coupled to the system circuitry through a cable.

1 17. The ultrasound diagnostic instrument as defined by claim 15, wherein
2 the transducer assembly is integral with the handheld module.

1 18. The ultrasound diagnostic instrument as defined by claim 12, wherein
2 the signal processing circuitry of the ECG module includes first amplification and filtering
3 circuitry for signals from the leads and second amplification and filtering circuitry for
4 processing signals from the first amplification and filtering circuitry for application to the
5 handheld module, the first and second amplification and filtering circuitry being optically
6 coupled.

1 19. The ultrasound instrument as defined by claim 18, wherein the first and
2 second amplification and filtering circuitry are being magnetically coupled.

1 20. The ultrasound instrument as defined by claim 18, wherein the
2 first and second amplification and filtering circuitry are being capacitively coupled.

1 21. The ultrasound diagnostic instrument as defined by claim 12, wherein
2 the transducer assembly is coupled to the system circuitry through a cable.

1 22. The ultrasound diagnostic instrument as defined by claim 12, wherein
2 the transducer assembly is integral with the handheld module.

1 23. The ultrasound diagnostic instrument as described in claim 12, wherein
2 said hand held module further comprises circuitry for performing spectral Doppler analysis
3 and allowing for simultaneous ECG readings to be overlaid on a spectral Doppler display.

1 24. For use with a handheld ultrasound diagnostic instrument, an
2 electrocardiograph (ECG) module comprising:
3 leads for receiving ECG signals from a patient;
4 ECG signal processing circuitry; and

5 a cable for applying ECG signals from the ECG signal processing circuitry to
6 the handheld module.

1 25. The ECG module as described in claim 24, wherein the ECG module
2 receives control, clock and power signals from the handheld ultrasound diagnostic
3 instrument.

1 26. The ECG module as defined by claim 25, wherein the signal
2 processing circuitry of the ECG module includes first amplification and filtering circuitry for
3 signals from the leads and second signal amplification and filtering circuitry for processing
4 signals from the first amplification and filtering circuitry for application to the handheld
5 ultrasound diagnostic instrument, the first and second amplification and filtering circuitry
6 being optically coupled.

1 27. The ultrasound instrument as defined by claim 26, wherein the first and
2 second amplification and filtering circuitry are being magnetically coupled.

1 28. The ultrasound instrument as defined by claim 26, wherein the first and
2 second amplification and filtering circuitry are being capacitively coupled.

1 29. The ECG module as defined by claim 26, wherein the first
2 amplification and filtering circuitry receives electrical power from the handheld module, the
3 electrical power being capacitively coupled to the first amplification and filtering circuitry.

1 30. The ECG module as defined by claim 24, wherein the signal
2 processing circuitry of the ECG module includes first amplification and filtering circuitry for
3 signals from leads and second amplification and filtering circuitry for processing signals from
4 the first amplification and filtering circuitry for application to the handheld ultrasound
5 diagnostic instrument, the first and second amplification and filtering circuitry being optically
6 coupled.

1 31. The ultrasound instrument as defined by claim 30, wherein the first and
2 second amplification and filtering circuitry are being magnetically coupled.

1 32. The ultrasound instrument as defined by claim 30, wherein the first and
2 second amplification and filtering circuitry are being capacitively coupled.

1 33. In an electrocardiograph (ECG) module having first signal processing
2 circuitry for processing ECG signals from a patient and second signal processing circuitry for
3 further processing of the ECG signals for diagnostic use, a power supply circuit for providing
4 electrical power from the system to the first signal processing circuitry comprising:

5 a) a serial inductive path for receiving a DC voltage and a shunt
6 capacitive path and a shunt switch connecting the serial inductive path to a power ground;

7 b) a first coupling capacitor for coupling the serial inductive path to the
8 first signal processing circuitry and a second coupling capacitor for coupling the power
9 ground to the first signal processing circuitry; and

10 c) a rectifying circuit in the first signal processing circuitry including a
11 forward polarity diode connecting the first coupling capacitor to a first terminal of a positive
12 charge capacitor and a reverse polarity diode coupling the first coupling capacitor to a first
13 terminal of a negative charge capacitor, and an isolated reference terminal connected to the
14 second coupling capacitor and to a second terminal of the positive charge capacitor and to a
15 second terminal of the negative charge capacitor whereby electrical power is coupled through
16 the coupling capacitors to the charge capacitors at the frequency of the shunt switch.

1 34. The power supply circuit as defined by claim 33, wherein the
2 electrocardiograph module is used with a handheld ultrasound diagnostic instrument and
3 includes patient isolation from the system power supply which meets the requirements of
4 ANSI/AAMI EC13 specification.

1 35. A power interface for coupling DC power from a non-isolated system
2 to signal processing circuitry isolated from the system power supply comprising:

3 chopping circuitry for chopping DC power supply voltage of the system;
4 coupling capacitors for coupling power supply voltage to isolation circuitry;

5 and

6 rectifying circuitry in the signal processing circuitry for receiving and
7 rectifying the capacitively coupled chopped DC voltage.

1 36. The power interface as defined by claim 35, wherein the chopping
2 circuitry comprises serially connected inductors connected to one coupling capacitor and a
3 shunt capacitor and a shunt switch connecting a common terminal of the serially connected
4 inductors to the power supply system ground and the second coupling capacitor.

1 37. A lightweight, handheld system for performing electrocardiography
2 comprising:
3 a handheld ultrasound device weighing less than seven pounds having a
4 transducer, a beamformer, an image processor and one or more digital signal processors for
5 signal filtering, detection and mapping; and
6 a portable electrocardiogram monitor weighing less than three pounds and
7 having at least three electrical leads for measuring electrical potential across a person's chest,
8 a differential amplifier for amplifying the measured electrical potential, a plurality of signal
9 filters and gain amplifiers, and a means for electronically isolating the measured signal from
10 other electrical inputs and interferences.

1 38. The system of claim 37, wherein the plurality of signal amplifiers
2 further comprise a bandpass filter, a highpass filter, and a lowpass notch filter.

1 39. A method of performing spectral Doppler analysis in a hand held
2 ultrasound system comprising the steps of:

- 3 (a) analyzing the display data to restructure the original power frequency
4 spectrum;
5 (b) performing a temporal smoothing on the frequency spectrum;
6 (c) determining the absolute value deviation for each frequency spectrum;
7 (d) determining the mean power per frequency spectrum;
8 (e) applying one of several fixed smoothing filters to each frequency
9 column;
10 (f) finding the maximum value before the mean of each frequency
11 spectrum;
12 (g) establishing a frequency spectrum threshold;
13 (h) employing a peak finding algorithm;
14 (i) applying a fixed width filter for temporal smoothing; and
15 (j) reversing the process of (a) to return the image data to the size
16 appropriate for the system display.

1 40. The method of claim 39, wherein step (b) is omitted.

1 41. In a programmable diagnostic ultrasound instrument having stored
2 software and data for operation control, a software security mechanism which restricts

modification of software or data including an algorithm which generates a keycode based on a unique system identifier which allows a person or agency to perform a system or data update.

42. The programmable diagnostic ultrasound instrument of claim 41, wherein the system or data update is performed through a detachable scanhead.

43. The programmable diagnostic ultrasound instrument of claim 41, wherein the software security mechanism is a signature generator.

44. The ultrasound instrument of claim 41, being a portable ultrasound instrument.

45. The ultrasound instrument of claim 41, being a hand held ultrasound instrument.

46. The ultrasound instrument of claim 41, weighing less than ten pounds (4.5 kg).

47. An ultrasound instrument having a software library and data for operational control stored on a persistent memory device, and having a means for securely enabling and disabling applications within the software library.

48. A programmable diagnostic ultrasound instrument having a plurality of diagnostic modes, wherein access to the diagnostic modes is controlled through a gate flag registry, the gate flag registry capable of modification through a verification procedure utilizing a secure means for extracting hidden bits from a keycode based on one or more unique system identifiers.

49. The programmable diagnostic ultrasound instrument of claim 48, wherein the verification procedure for extracting hidden bits from a keycode further comprises a compound algorithm including a signature generator, an encryption algorithm and a reversible logic operation, the compound algorithm being capable of verifying a keycode when operated in a decryption mode, and able to produce a verification data string having error detection bits, signature bits, and option bits.

1 50. The compound algorithm of claim 49, wherein more than one signature
2 generator is used.

1 51. The compound algorithm of claim 49, wherein more than one
2 encryption algorithm is used.

1 52. The programmable diagnostic ultrasound instrument of claim 49,
2 wherein the compound algorithm further comprises a plurality of algorithms dependent upon
3 each other for input values of various stages of their logic, a first algorithm producing a first
4 bit string used by the second algorithm to produce a second bit string, the second bit string
5 being required by the first algorithm to produce a new bit string n_{x+1} needed by said second
6 algorithm to produce a new bit string n_{x+2} , wherein the logic strings (n_{x+y}) are used by said
7 first algorithm and said second algorithm until the plurality of algorithms complete all logic
8 operations and produce a final bit string n_{xf} .

1 53. The programmable diagnostic ultrasound instrument of claim 52,
2 wherein the logic of the dependent algorithms may be executed in reverse to produce any one
3 of the input values produced by the other algorithm, or any one of the starting input values.

1 54. The programmable diagnostic ultrasound instrument of claim 52,
2 wherein at least one of the algorithms is a data encryption algorithm.

1 55. The compound algorithm of claim 49, wherein the reversible logic
2 operation is any logic operation capable of combining the bit strings of the signature
3 generator and the encryption algorithm to produce a keycode when run in encryption mode,
4 and produce the necessary verification data string when run in decryption mode.

1 56. The programmable diagnostic ultrasound instrument of claim 48,
2 wherein the verification procedure is executed through an application specific integrated
3 circuit (ASIC) that draws instrument specific information from either a software data
4 structure, or a hardware data registry.

1 57. The ultrasound instrument of claim 48, being a portable ultrasound
2 instrument.

1 58. The ultrasound instrument of claim 48, being a hand held ultrasound
2 instrument.

1 59. The ultrasound instrument of claim 48, weighing less than ten pounds
2 (4.5 kg).

1 60. In a programmable diagnostic ultrasound instrument having stored
2 software and data for operation control, a software security mechanism which restricts
3 modification of software or data utilizing a 64-bit mixing algorithm and a bit-wise signature
4 generator within an architecture using a X-OR logic to perform reversible encryption and
5 decryption operations, thereby allowing a user to change software or data using a short
6 sequence of numbers while providing the security of a large bit string verification scheme
7 enabling signature verification, error correction and licensing verification.

1 61. The programmable diagnostic ultrasound instrument of claim 60,
2 wherein said instrument is a hand held device.

1 62. The programmable diagnostic ultrasound instrument of claim 60,
2 weighing less than ten pounds (4.5 kg).

1 63. A system for the tracking diagnostic modes in one or more
2 programmable diagnostic ultrasound instrument(s) comprising:

3 a) a general purpose computer having a means for generating a unique
4 keycode for each programmable diagnostic ultrasound instrument, the keycode having
5 encrypted error detection bits, signature bits and options bits for enabling diagnostic modes in
6 a particular instrument;

7 b) at least one programmable diagnostic ultrasound instrument having a
8 plurality of diagnostic modes that can be enabled or disabled upon successful verification of
9 the keycode, the verification procedure utilizing a secure means for extracting hidden bits
10 used to modify a gate flag registry from the keycode; and

11 c) a data structure for centrally recording and tracking diagnostic modes
12 of each diagnostic ultrasound instrument.

1 64. A system as described in claim 63, wherein each programmable
2 diagnostic ultrasound instrument links into a central database and receives a verification code

3 from the central database before any changes in the software libraries of the diagnostic
4 ultrasound devices may be implemented.

1 65. The system as described in claim 64, wherein a person links into the
2 central database by calling a database controller to receive a verification code via a telephone
3 or fax machine.

1 66. The system of claim 64, wherein the verification code is a keycode
2 which must be verified by the diagnostic ultrasound device through a logic process utilizing
3 unique system identifiers, said unique system identifiers being unique for each said
4 diagnostic ultrasound device.

1 67. A method of upgrading the functional software of a programmable
2 diagnostic ultrasound instrument comprising the steps of:

3 (a) generating a keycode generation algorithm comprising at least one
4 encryption algorithm, at least one signature generator, and a reversible logic operation for
5 mixing a bit string produced by said encryption algorithm and a bit string produce by said
6 signature generator;

7 (b) generating a keycode using the keycode generation algorithm, said
8 keycode utilizing data specific to a programmable diagnostic ultrasound instrument and data
9 relating to a desired software upgrade;

10 (c) inputting the keycode obtained from the step (b) into the
11 programmable diagnostic ultrasound instrument; and

12 (d) verifying the keycode generated by step (b) in the programmable
13 diagnostic ultrasound instrument, using a reversing algorithm of step (a) to compare and
14 verify the signature bits, error detection bits and option bits.

1 68. The method of claim 67, wherein step (b) further comprises the steps
2 of:

3 (b1) inputting instrument specific information into a keycode encryption
4 algorithm;

5 (b2) providing one or more secret constants to the keycode encryption
6 algorithm;

7 (b3) executing the operation of the encryption algorithm;

10062179-020102

8 (b4) choosing a series of options to enable, each option coding for a desired
9 software upgrade, in the programmable diagnostic ultrasound instrument and entering the
10 series of options into a signature generator algorithm;

11 (b5) generating a first bit string in the signature generator having an equal
12 length to a second bit string produced by the encryption algorithm;

13 (b6) executing a X-OR function on the first and second bit strings to
14 produce a third bit string;

15 (b7) converting the third bit string to a decimal string; and

16 (b8) producing a keycode.

1 69. The method of claim 67, wherein step (c) further comprises the step of:

2 (c1) loading a new software application into the programmable diagnostic
3 ultrasound instrument; and

4 (c2) enabling the new software application by inputting the keycode
5 obtained from the vendor, into the programmable diagnostic ultrasound instrument.

1 70. The method of claim 67, wherein step (d) further comprises the steps
2 of;

3 (d1) converting the license string into the X-or bit string;

4 (d2) generating a second bit string by running the encryption algorithm
5 internally within the programmable diagnostic ultrasound instrument;

6 (d3) reversing the X-or logic on the X-or bit string and the second bit string
7 to produce a first bit string;

8 (d4) isolating the signature bits, option bits and error detection bits of the
9 first bit string;

10 (d5) comparing the signature bits, the option bits and the error detection bits
11 generated by the reverse X-or first bit string to the internally generated first bit string; and

12 (d6) enabling the necessary options programmed through the option bits.

1 71. The method of claim 67, further comprising the step of recording in a
2 database the particular options that are enabled on a particular programmable diagnostic
3 ultrasound instrument.

1 72. The method of claim 67, wherein the programmable diagnostic
2 ultrasound device is portable.

1 73. The method of claim 67, wherein the programmable diagnostic
2 ultrasound device is hand held.

1 74. The method of claim 67, wherein the programmable diagnostic
2 ultrasound device is less than ten pounds (4.5 kg).

1 75. The method of claim 67, wherein the logic is executed within an
2 application specific integrated circuit (ASIC) using one or more fixed registries for input
3 values.

2010020-62729007